NDS SURGICAL - IMAGING

510(K) SUMMARY

JUN 7 2013

A. Manufacturer:	NDS Surgical Imaging, LLC 5750 Hellyer Avenue San Jose, CA 95138 USA
B. Submitted By:	Jim Leng Regulatory Engineer/NDS Surgical Imaging, LLC
B1, Address:	NDS Surgical Imaging, LLC 5750 Hellyer Avenue San Jose, CA 95138 USA
C. Date of Preparation:	April 17, 2013
D. Contact Information:	Tel: 408-776-0085 Fax: 408-776-9878
E. Classification:	Endoscope and Accessories
F. Common Name:	UWB Wireless Device
G. Proprietary Name:	ZeroWire Duo Wireless HD Video Transfer System
H. Classification number:	21 CFR 876.1500
I Product Code:	GCJ
J. Substantial Equivalence:	Predicate K100195 ZeroWire Duo Wireless HD Video Transfer System.
K. Device Description:	Model Wu-vwx-yz, where u = R or T; v=P or M; w=1 to 3; x= 1 to 6; y= 0 to 2; z=1 to 3, the ZeroWire wireless device is designed as a wireless transmitter and receiver pair which allows delivery of a video signal over a radio frequency link to video destination such as Radiance and EndoVue devices. The device can operate on up to 9 channels.
L. Indications for Use:	The NDSsi ZeroWire Duo Wireless HD Video Transfer System is a paired transmitter and receiver, intended for delivery of video signals over a radio-frequency link to a video display during endoscopic and general surgical

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procedures. The ZeroWire wireless device is a non-sterile reusable device not intended for use in the sterile field. It is intended for use by qualified physicians having complete knowledge of these surgical procedures.

M. Technological Characteristics: ZeroWire Duo wireless devices are an advance medical grade wireless video transfer solution for minimally invasive surgery and interventional procedures. By utilizing the reserved UWB frequency spectrum, ZeroWire provides a wireless video link that is resistant to interference from other devices. It enhances clinical efficiency and safety in the OR by eliminating the need for a video cable. The proprietary memory-enabled pairing system makes installation quick and easy. ZeroWire technology provides the medical grade quality of service and is specifically designed for the video transmission challenges of the surgical environment.

N. Clinical information: Clinical data is not needed for this type of wireless device by 510(k) submission guidance document. However, this submission provides test results in clinical environment to demonstrate the device is substantial equivalent to the predicate device.

O. Conclusion:, The device software (firmware) was modified to increase from 3 channels to 9 channels, and there is no hardware change. Based upon validations results from both design and clinical, ZeroWire device demonstrates performance, safety, and effectiveness that is equivalent to the predicate device – original ZeroWire submission K100195.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

NDS Surgical Imaging, LLC
% Mr. Jim Leng
Regulatory Engineer
5750 Hellyer Avenue
San Jose, California 95138

June 7, 2013

Re: K131115
Trade/Device Name: ZeroWire Duo Wireless HD Video Transfer System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: May 15, 2013
Received: May 20, 2013

Dear Mr. Leng:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (K131115): K131115

Device Name: ZeroWire Duo Wireless HD Video Transfer System

Indications For Use:

The NDSsi ZeroWire Duo Wireless HD Video Transfer System is a paired transmitter and receiver, intended for delivery of video signals over a radio-frequency link to a video display during endoscopic and general surgical procedures. The ZeroWire wireless device is a non-sterile reusable device not intended for use in the sterile field. It is intended for use by qualified physicians having complete knowledge of these surgical procedures.

Prescription Use ___√___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden
2013.06.07 14:49:07 -04'00'

(Division Sign-Off) for MXM
Division of Surgical Devices
510(k) Number ___K131115____

5750 Hellyer Avenue ■ San Jose, CA 95138 ■ www.ndssi.com

RADIANCE DOME